UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOSEPH R. BYRUM

Appeal No. 2004-1772
Application No. 09/552,087

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 3, 5-7, 9, 10, and 12-20, which are all the claims pending in the application.

Claims 3, 7 and 12 are illustrative of the subject matter on appeal and are reproduced below:

3. A transformed plant cell having a nucleic acid molecule which comprises:

(A) an exogenous promoter region which functions in said cell to cause the production of a mRNA molecule, wherein said promoter nucleic acid molecule comprises SEQ ID N0: 1 or a complement thereof; which is linked to

(B) a structural nucleic acid molecule encoding a protein or peptide; which is linked to

(C) a 3' non-translated sequence that functions in said cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

7. A transformed plant having a nucleic acid molecule which comprises:
(A) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule, wherein said promoter nucleic acid molecule comprises SEQ ID NO: 1, or a complement thereof; which is linked to
(B) a structural nucleic acid molecule encoding a protein or peptide; which is linked to
(C) a 3' non-translated sequence that functions in a plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

12. A substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 70% identity with a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof.

No prior art is relied upon in support of the examiner's position.

GROUNDS OF REJECTION

Claims 3, 5-7, 9-10 and 12-20 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

Claims 12-19 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to provide an adequate written description of the claimed invention.

We reverse the written description rejection, and remand the application to the examiner for further consideration of the utility and enablement rejections.

DISCUSSION

Written Description:

The examiner rejected the claims as inadequately described, on the basis that the claimed nucleic acids

> comprise SEQ ID NO: 1 or a nucleic acid related to SEQ ID NO: 1 by a particular range of identity (i.e. 100% to 80% identity, as in claim 13)[1]. This genus is sufficiently broad so as to encompass a multitude of variants of SEQ ID NO:1, as well as any full length coding sequence, mRNA, promoter, or genomic DNA of which SEQ ID NO: 1 is a portion, or of which the recited polynucleotides with identity to SEQ ID NO: 1 are portions. This large genus is represented in the specification by one species, a nucleic acid consisting of SEQ ID NO: 1.

Answer, bridging paragraph, pages 8-9 .

We will reverse this rejection. The written description requirement of 35 U.S.C. § 112, first paragraph, does not require a description of the complete structure of every species within a chemical genus. See Utter v. Hiraga, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) ("A specification may, within the meaning of 35 U.S.C. § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.").

The Federal Circuit has held that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which

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[1] While the examiner refers to claim 13, which depends from claim 12, we note as illustrated above, that claim 12 is broader than claim 13, in that it relates to a "sequence having between 100% and 70% identity with a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof."

features constitute a substantial portion of the genus." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Our appellate reviewing court has also held that the complete structure of a claimed DNA is not necessarily required. The court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002) (emphasis omitted, alterations in original).

With respect to the claimed sequences that have 70% to 100% identity with SEQ ID NO:1, the Lilly court held that a genus could be described via "recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. The Enzo court held that such a description could take the form of "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." 296 F.3d at 1324, 63 USPQ2d at 1613. In this case, the complete structure of SEQ ID NO:1 has been described, and the nucleic acids of the claimed genus share 70 or more percent identity with the structure of SEQ ID NO:1. Thus, the structural features that are common to the genus make up 70% of the structure

of the claimed polypeptides. The examiner has not adequately explained why this degree of structural similarity is inadequate to "constitute a substantial portion of the genus," as required by Lilly.

Accordingly, we reverse the rejection of claims 12-19 under 35 U.S.C. § 112, first paragraph, as the specification fails to provide an adequate written description of the claimed invention.

Utility:

The issues of whether a disclosure satisfies the "how to use" provision of 35 U.S.C. § 112, and the utility requirement of 35 U.S.C. § 101, are closely related. See In re Swartz, 232 F.3d 862, 863, 56 USPQ2d 1703 (Fed. Cir. 2000), Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358, 52 USPQ2d 1029, 1034 (Fed, Cir 1999), Newman v. Quigg, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989). Under the utility requirement, our appellate reviewing court, has held that it makes no sense to require claims to set forth inventions that satisfy all the disclosed objectives, but that "[w]hen a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown." Raytheon Co. v. Roper Corp., 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983).

As set forth in In re Langer, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974), emphasis in original:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of Section 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question

> the objective truth of the statement of utility or its scope. Assuming that sufficient reason to question the statement of utility and its scope does exist, a rejection for lack of utility under Section 101 will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the statement of utility and its scope as found in the specification are true. Cf. In re Marzocchi, 58 CCPA 1069, 1073, 439 F.2d 220, 223, 169 USPQ 367, 369 (1971) (involving the enablement requirement of 35 U.S.C. 112, first paragraph).

According to the examiner (Answer, page 6), "[t]here has been no specific assertion that in fact SEQ ID NO: 1 is a promoter, aside from the claims." Contrary to the examiner's assertion, however, appellant's specification does set forth a statement of utility that corresponds in scope to the subject matter claimed. Specifically, appellant discloses (specification, page 16), "[a]nother class of agents of the present invention are nucleic acid molecules having promoter regions or partial promoter regions, including those located within SEQ ID NO: 1...." As set forth in Raytheon, "[w]hen a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown." Similarly, as set forth in Johns Hopkins Univ. v. CellPro Inc., 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1714 (Fed. Cir. 1998), "[t]he enablement requirement is met if the description enables any mode of making and using the invention."

Therefore, it is the examiner's initial burden to establish that those skilled in this art would question the objective truth of the asserted utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence."). In our opinion, the examiner has not provided sufficient evidence to

show that one of ordinary skill in the art would reasonably doubt that a nucleic acid molecule comprising SEQ ID NO: 1 would not have utility as a promoter as disclosed in appellants' specification.

To the contrary, the examiner has simply asserted (Answer, page 5) that "further experimentation would be required to reasonably confirm that SEQ ID NO: 1, or its complement, or fragments of either would function as a promoter as required by the claims. The specification does not provide any guidance as to the use of SEQ ID NO: 1, its complement or fragments thereof as promoters." Based on this assertion, the examiner concludes, "[t]he use of ... SEQ ID NO: 1 as a promoter is not a specific or substantial utility since further experimentation would be required to confirm that in fact SEQ ID NO: 1 has the ability to cause the production of an mRNA molecule...." Answer, page 6. While appellant has disclosed the characteristics of promoters within the scope of the claimed invention at pages 16-17 of the specification, the examiner fails to address this section of appellant's specification, or to establish a factual basis on this record to support the assertion that SEQ ID NO: 1 does not contain a promoter element.

According to the examiner (id.), "one would have to determine if the ... [promoter] is tissue specific or constitutive, for example, or if it is an inducible promoter, and under what circumstances it is induced or repressed in order to make use of the claimed plants." The examiner finds (id.), "[e]ach of these determinations is highly unpredictable, from the determination ... of the type of promoter it may be to the determination of fragments of the promoter that confer

promotion activity." The examiner, however, fails to establish a factual basis on this record to support these assertions.

Further, our review of this record is hindered by the examiner's failure to apply any type of claim construction to the claims now before us on appeal. In this regard, we note that claims 3 and 7, as well as the claims that depend from these claims, require in part "(A)" of each claim "an exogenous promoter region which functions ... to cause the production of a mRNA molecule." According to part "(A)" of these claims the promoter "comprises SEQ ID NO: 1 or a complement thereof...." We find no clear disclosure in the specification that SEQ ID NO: 1 is capable of functioning as a promoter region in plant cells to cause the production of a mRNA molecule. As we understand it, part "(A)" of these claims is open to at least three possible interpretations:

1. SEQ ID NO: 1 contains a promoter region which does function in plant cells to cause the production of a mRNA molecule,

2. SEQ ID NO: 1 does not contain a "promoter region," but instead contains a "regulatory element"[2] that acts in concert with a promoter region operably attached, either 5' or 3', to SEQ ID NO: 1, and thereby serves to regulate the expression of a mRNA molecule. For example, SEQ ID NO: 1 is an enhancer regions which is incapable of acts on a promoter, but is insufficient to function in plant cells to cause the production of a mRNA molecule on its own, or

3. SEQ ID NO: 1 contains neither a promoter region nor a regulatory element and simply serves as a filler sequence between the promoter region and a structural nucleic acid molecule, as defined in part "(B)" of these claims. For example, SEQ ID NO: 1 is incapable of functioning in plant cells to cause the production of a mRNA molecule, but instead serves only to

[2] See e.g. appellant's specification, page 17.

> maintain the proper distance between a promoter and a "regulatory element."

It may be that the examiner is of the opinion that SEQ ID NO: 1 does not contain a promoter element. Cf. interpretation 3 above. The examiner, however, has not provided a sufficient evidentiary basis on this record to establish that SEQ ID NO: 1 does not contain a promoter or regulatory region, or if it does, why a person of ordinary skill in the art would reasonably doubt that the sequence would not function as a promoter or regulatory region.

For the foregoing reasons we remand the application to the examiner for further consideration. Prior to any further action on the merits, we encourage the examiner to take a step back and reconsider the claimed invention together with appellant's specification and the relevant prior art. In this regard, we remind the examiner as set forth in In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989), "claims must be interpreted as broadly as they reasonably, allow, in order to achieve complete exploration of applicant's invention and its relationship to prior art, so that ambiguities can be recognized, scope and breadth of language explored, and clarification imposed." Accordingly, prior to taking any action on the record, we encourage the examiner to determine the broadest reasonable interpretation of the claimed invention and to include an analysis of this claim construction in any subsequent Office Action. If, after the examiner has evaluated the scope of the claim, the examiner believes that a rejection is necessary, the examiner should include on this record, an analysis of the claim construction together with a reasoned, fact-

based analysis of claimed invention together with the evidence necessary to support any such rejection.

In addition, we note that appellant has disclosed and argued that a nucleic acid molecule comprising SEQ ID NO: 1 has a number of utilities, e.g., for identifying the presence or absence of a polymorphism, or as probes for other molecules or as a source for primers (see e.g., Brief, pages 7-11). These issues and arguments, however, bear a close resemblance to those presented in Ex parte Fisher, 72 USPQ2d 1020 (Bd. Pat. App. & Int. 2004) (affirming the rejection of claim 1 under 35 U.S.C. § 101 and § 112, first paragraph.). Accordingly, we encourage both the examiner and appellants to take the opportunity to reconsider their arguments on this record and to take into account the effect, if any, that Fisher may have on the issues under 35 U.S.C. § 101 and § 112, first paragraph.

REVERSED-IN-PART and REMANDED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

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